

### **REMARKS**

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Please cancel claims 1, 4, 7, 16, 34, 37-40, and 42 without prejudice. Applicant reserves the right to pursue this subject matter in a continuation application. Applicant amends claims 2-3, 5-6, 8, 11-13, 18-21, 23, 25-33, 35-36, and 41. Support can be found throughout the specification, including at page 4, lines 8-20. No new matter has been added through the amendments. Claims 2-3, 5-6, 8-15, 17-33, 35-36, and 41 will be pending upon entry of this amendment.

Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. §§ 101 and 112, first paragraph.

#### **Rejections under 35 U.S.C. §§ 101 and 112, first paragraph**

The Examiner rejects claims 1-8 and 20-42 under 35 U.S.C. § 101, for an alleged lack of statutory matter, and § 112, first paragraph, for an alleged lack of enablement. Specifically, the Examiner contends that the term "use of" is not among the statutory class of inventions. The Examiner further contends that the claimed invention is not supported by an asserted or established utility, thereby one of skill in the art would not know how to make and use the claimed invention. As suggested by the Examiner, Applicant has amended the claims originally filed in the PCT application to recite the term "method of" instead of "use of". As the Examiner suggested, this amendment should render said rejections moot. In view of the amended claims, Applicant respectfully request removal of these rejections.

#### **Rejections under 35 U.S.C. § 112, first paragraph**

The Examiner rejects claims 1-42 under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description. Specifically, the Examiner contends that Applicant has not provided a description of the structure of a representative number of compounds, or a description of the chemical and/or physical characteristics of a representative number of compounds, or a description of how to obtain a representative number of specific compounds ("an acetylcholine esterase antagonist"). Further, the Examiner rejects claims 17-19 since the specification does not contain any working examples to describe such claimed subject matter. Additionally, the

Examiner rejects claims 1-8 for allegedly failing to describe the claimed subject matter to convey possession of the claimed invention to one of skill in the art. Applicant respectfully traverses.

The written description requirement requires that Applicants' specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, that he or she was in possession of the invention. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Moreover, as noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, "Written Description" Requirement ("the guidelines"), there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, 66(4) *Fed Reg.* 1099, 1105 (2001); see also, *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976). The guidelines further state that "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicants' disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97.

**A. Claims 1-42.** In summary, the Examiner alleges that the term "an acetylcholine esterase antagonist" is not structurally (structure/physical characteristics) described to convey possession of the entire genus of the claimed subject matter.

To have possession of members of a claimed genus, the specification ***need not describe all of the species that the genus encompasses***. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) [***emphasis added***]. Applicant respectfully submits that the structure is not relevant to the claim, but rather the mechanism of action is relevant to the claim. Applicant is claiming a compound that inhibits acetylcholine esterase. Applicant discloses a working example demonstrating the reduction of insulin resistance in rats using the acetylcholine esterase antagonist neostigmine. Further, Applicant discloses many compounds having this same functionality, acetylcholine esterase antagonism, at p. 10, lines 6-14. Thereby, Applicant has described an array of known inhibitors of acetylcholine esterase. Applicant respectfully submits that the specification conveys a compound having the ability to inhibit acetylcholine esterase will reduce insulin resistance and has sufficiently described a number of compounds that will inhibit acetylcholine esterase. Applicants respectfully request removal of this rejection.

**B. Claims 17-19.** The Examiner rejects claims 17-19 solely because the specification lacks a working example of this claimed subject matter. The Examiner rejects claims 17-19 for an alleged lack of enablement, but the Examiner's reasoning is due to a lack of description. For example, "Applicant has not provided any working examples which would *describe* one of ordinary skill in the art an embodiment that met all of the limitations thereof" (Office Action at p. 17-18) and "the Applicant has not *described* with sufficient clarity" (Office Action at p. 6, lines 19-20). The Examiner also rejected claims 1-8 for an alleged lack of written description under the same subheading as the rejection of claims 17-19. Therefore, Applicant presumes a typographical error, and that claims 17-19 are rejected for an alleged lack of written description.

Applicants respectfully assert that a working example is not necessary to provide a sufficient written description. The Federal Circuit has explicitly ruled that working examples are not required to meet the written description requirement. *Falkner v. Inglis*, 448 F.3d, 1357, 1366 (Fed. Cir. 2006). "[R]eduction to practice ordinarily provides the best evidence that an invention is complete. . . . it does not follow that proof of reduction to practice is necessary in every case." *Pfaff v. Wells Elecs.*, 525 U.S. 55, 66 (1998). Claims 17-19 are supported throughout the disclosure, including at p. 4, lines 8-20, and at p. 8, lines 6-30. Applicants respectfully request removal of this rejection.

**C. Claims 1-8.** Upon entry of this amendment, claims 2-3, 5-6, and 8 will be pending, and the Examiner has not presented an argument for lack of written description by a preponderance of the evidence. The guidelines state that "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* 1099, 1107; 191 USPQ 90, 97 (emphasis added). In the Office Action at p. 6, lines 12-16, the Examiner simply concludes that claims 1-8 allegedly are not described in such a way to reasonably convey possession of the claimed subject matter. There is no further reasoning. Applicants respectfully submit that the Examiner has not met the burden of explaining why the specification does not sufficiently describe the claimed subject matter by a preponderance of the evidence.

Applicants further submit that claims 2-3, 5-6, and 8 are sufficiently described in the specification. Support for these claims can be found at p. 4, lines 8-20 in the Summary of the Invention and at p. 8, line 13 to p. 14, line 15 in the Detailed Description. Further support for these claims can be found at Example 3, p. 20-21. For at least these reasons, Applicant respectfully asserts that the specification conveys possession of the claimed subject matter for claims 2-3, 5-6 and 8.

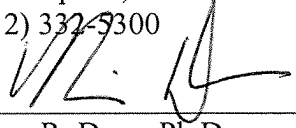
In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

### Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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